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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,146

05/05/2006

Shyam S. Mohapatra

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

10/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/544,146	<b>Applicant(s)</b> MOHAPATRA ET AL.	
	<b>Examiner</b> Richard Schnizer, Ph. D.	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 8, 10, 11, 16, 17, 22-30, 34, 36, 37, 42, 45, 46 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,7,8,10,11,16,17,22-30,34,36,37,42,45,46 and 48-50.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 7, 8, 10, 11, 16, 17, 22, 23, and 24 in part, and 50, drawn to a vector comprising a plurality of expression cassettes including at least one gene promoting cassette and at least one gene suppressing cassette, wherein both cassettes comprise a promoter operably linked to a polynucleotide, and wherein in the gene suppressing cassette the polynucleotide encodes an siRNA targeted to a gene other than a Dengue virus gene.

Group 2, claim(s) 1, 7, 8, 10, 11, 16, 17, 22, 23, 24 in part, 25-30, and 50, drawn to a vector comprising at least one gene suppressing cassette comprising a promoter operably linked to a polynucleotide encoding an siRNA targeted to a Dengue virus gene.

Group 3, claim(s) 34, 36, and 37, 42, 45, and 46, drawn to a first method of using a vector comprising a plurality of expression cassettes including at least one gene promoting cassette and at least one gene suppressing cassette, wherein both cassettes comprise a promoter operably linked to a polynucleotide, and wherein in the gene suppressing cassette the polynucleotide encodes an siRNA targeted to a gene other than a Dengue virus gene.

Group 4, claims 42, 45, and 46, drawn to a first method of using a vector comprising at least one gene suppressing cassette comprising a promoter operably linked to a polynucleotide encoding an siRNA targeted to a Dengue virus gene.

Group 5, claim 48, drawn to a first method of making a vector comprising a plurality of expression cassettes including at least one gene promoting cassette and at least one gene suppressing cassette, wherein both cassettes comprise a promoter operably linked to a polynucleotide, and wherein in the gene suppressing cassette the polynucleotide encodes an siRNA targeted to a gene other than a Dengue virus gene.

Art Unit: 1635

Group 6, claim 49, drawn to a first method of making a vector comprising at least one gene suppressing cassette comprising a promoter operably linked to a polynucleotide encoding an siRNA targeted to a Dengue virus gene.

Claims 1, 7, 8, 10, 11, 16, 17, 22-24, and 50 are generic to inventions 1 and 2. Should Applicant elect either of these groups, the claims will be examined to the extent that they read on the elected group.

If Applicant elects a group comprising claim 24 or claim 30, then an election of a recited SEQ ID NO: is required. Claim 24 recites SEQ ID NOS: 1-4 and claim 30 recites SEQ ID NOS: 1 and 2. Note that SEQ ID NOS: 1 and 2 are in group 1, and SEQ ID NOS: 3 and 4 are in group 2.

The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Paddison et al (PNAS 99(3): 1443-1448, 2002) taught a vector encoding an expression cassette for a hairpin siRNA directed to green fluorescent protein, and an expression cassette for G418 resistance, thereby anticipating group 1. See paragraph bridging columns 1 and 2 on page 1444, and page 1445, column 1, first full paragraph. Adelman et al (J. Virol. 76(24): 12925-12933, 2002) taught a vector comprising a promoter driving expression of aminocyclitol phosphotransferase (hygromycin resistance) and a second expression cassette driving expression of an siRNA directed to Dengue virus prM gene, thereby anticipating group 2. See Fig. 1C on page 12926, and also page 12928, column 2, first sentence of Results. Because each group is anticipated by the prior art, they cannot be linked by a special technical feature. Regarding groups 3-6, note that 37 CFR 1.475(b) does not allow for grouping of different classes of invention (such as a product and a method of use, or a product and a method of making) when the two classes are not joined by a special technical feature.

Unity of invention is lacking between SEQ ID NOS: 1-4 because these sequences are hairpin RNAs directed to independent and distinct target sites, having independent and distinct sequences. Unity of invention exists where compounds (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. IN this case, each siRNA is structurally and functionally distinct, and is target to a different site.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the

Art Unit: 1635

hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.  
Primary Examiner  
Art Unit 1635